

Please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend claims 1, 3, 5, 6, 7, 8, 9, 10, 11, 47, and 93 pursuant to 37 C.F.R. 1.121 as follows (see the accompanying "marked up" version pursuant to 1.121):

1. A sustained-release therapeutic nail varnish composition comprising:

(a) a pharmaceutically effective agent selected from the group consisting of an antifungal agent, a keratolytic agent, and mixtures thereof;

(b) greater than 3% (w/w) of a humectant;

(c) water;

(d) a polymeric film-forming agent; and

(e) a volatile solvent;

said film-forming agent being selected so as to form a film upon application of said composition on a nail and evaporation of said volatile solvent, said film configured to trap water from said composition and maintain it in contact with said nail.

3. The nail varnish of claim 1, wherein said antifungal agent is selected from the group consisting of amphotericin B, butefanine, butoconazole, carbol-fuchsin, ciclopirox, clioquinol, clotrimazole, econazole, gentian violet, ketoconazole, miconazole, naftifine, nystatin, oxiconazole, sodium thiosulfate, terbinafine, terconazole, tolnaftate, undecylenic acid, therapeutically acceptable salts

thereof, derivatives thereof and mixtures thereof.

5. The nail varnish of claim 1, wherein said antifungal agent is present in an amount of less than about 1% of the total weight of the composition.

6. The nail varnish of claim 1, wherein said antifungal agent is present in an amount of less than about 5% of the total weight of non-volatile components.

B₃ 7. The nail varnish of claim 1, wherein said keratolytic agent is selected from the group consisting of urea, sulfur, salicylic acid, podophyllum resin and mixtures thereof.

8. The nail varnish of claim 1, wherein said keratolytic agent is urea.

9. The nail varnish of claim 1, wherein said keratolytic agent is present in an amount of less than about 1% of the total weight of the composition.

10. The nail varnish of claim 1, wherein said keratolytic agent is present in an amount of from about 0.05% to about 5% of the total weight of the non-volatile components.

11. A nail varnish of claim 1, wherein said pharmaceutically effective agent further comprises an antibacterial agent, an antiviral agent, an antiviral agent, an antipsoriatic agent or mixtures thereof.

*Ant
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47. A sustained-release therapeutic nail varnish composition comprising:

- (a) an antifungal agent;
- (b) a keratolytic agent;
- (c) greater than 3% (w/w) of a humectant ;
- (d) water;
- (e) a polymeric film-forming agent; and
- (f) a volatile solvent;

B4
said film-forming agent being selected so as to form a film upon application of said composition on a nail and evaporation of said volatile solvent, said film configured to trap water from said composition and maintain it in contact with said nail.

*Ant
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93. A method of preparing a sustained release therapeutic varnish or spray formulation for treating the nail and surrounding tissues, comprising the steps of:

- (a) preparing a solution comprising one or more volatile solvents;
- (b) adding water to the solution prepared in (a);

(c) dissolving a keratolytic agent, an antifungal agent and excipients in the solution prepared in (b);

(d) adding an humectant to the solution prepared in (c); and

(e) dissolving a polymeric film forming agent in the solution prepared in (d);

said film-forming agent being selected so as to form a film upon application of the formulation on a nail and evaporation of said volatile solvent, said film configured to trap water in contact with the nail and the surrounding tissues.

Please cancel claim 2.

Please add the following claims:

94. (New) The sustained-release therapeutic nail varnish composition of claim 1 further comprising an excipient.

95. (New) The sustained-release therapeutic nail varnish composition of claim 47 further comprising an excipient.

96. (New) A sustained-release therapeutic nail varnish composition comprising:

- (a) an antifungal agent;
- (b) a keratolytic agent;
- (c) a humectant;
- (d) a polymeric film forming agent;
- (e) water; and